

«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» -«Country_name»

Reference: 92196708 -FA

xx December 2017

Field Safety Notice - Urgent Medical Device Recall SpyScope™ DS Access and Delivery Catheter

Dear «Users_Name»,

Boston Scientific is initiating a voluntary removal of certain batches of SpyScope DS Catheters due to the potential for these devices to not perform as intended. An internal investigation found that the working channel sleeve may not be adequately bonded inside of these devices. This may result in the working channel sleeve protruding from the camera cap located at the distal tip of the catheter.

The most common injury reported has been minor tissue damage caused by the protruding working channel sleeve scraping along the duct walls during the procedure. The most serious injury that has been reported is significant bleeding resulting in medical or surgical intervention, including hospital admission and additional procedures.

Our records indicate that your facility received some of the concerned product. The **table below provides a complete list of all affected products**, including Product Description and Material Number (UPN). Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Further distribution or use of any remaining affected product should cease immediately.

Product Description	Material Number (UPN)	Batch	Expiration Date Range
SpyScope™ DS Access and Delivery Catheter	M00546600	See Attachment 1	See Attachment 1

INSTRUCTIONS:

- 1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.
- 2- **Please complete the attached Verification Form even if you do not have any product to return.**
- 3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **xx January 2018**.
- 4- **If you have products to return**, please package them in an appropriate shipping box and **contact «Customer_Service_Tel» of your local Boston Scientific office**, to arrange return.
- 5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1 – Affected Product Listing
SpyScope™ DS
Access and Delivery Catheter

UPN	Batch				Expiration Date Range
<p align="center"> SpyScope™ DS <i>Access and Delivery Catheter</i> M00546600 </p>	21071349	21186002	21264281	21339969	<p align="center"> August 29, 2019 To November 21, 2019 </p>
	21072506	21186199	21264826	21346857	
	21097205	21186874	21268628	21348369	
	21099913	21189216	21269880	21348655	
	21101809	21192332	21275009	21351508	
	21104860	21194784	21279183	21354138	
	21106212	21196427	21280166	21355128	
	21111667	21196815	21282419	21356067	
	21112353	21197475	21284302	21359495	
	21120166	21198355	21285174	21360857	
	21121467	21201164	21285708	21361914	
	21125598	21203598	21287283	21366469	
	21129863	21204762	21291325	21368941	
	21134585	21207916	21291903	21372468	
	21136699	21210287	21295990	21373463	
	21139834	21212151	21301969	21373946	
	21143014	21215249	21302617	21377827	
	21150144	21216252	21305351	21380698	
	21150932	21218379	21307321	21381638	
	21156170	21220903	21308963	21385327	
	21159396	21221247	21310860	21387164	
	21160496	21226282	21311361	21387745	
	21163684	21227147	21313025	21391319	
	21164861	21233949	21313392	21393249	
	21165772	21235402	21315518	21393900	
	21168729	21237929	21316968	21395015	
	21169977	21240546	21317017	21395016	
	21170814	21241587	21322828	21401047	
	21174026	21245984	21324197	21401048	
	21175845	21246770	21324851	21401049	
	21176842	21249893	21329021	21413940	
	21180343	21251968	21329708	21414750	
21181148	21253001	21332229	21420240		
21181151	21254244	21334848			
21181253	21257214	21335787			
21181677	21260915	21338493			